

interfering binding of variants and a luminescent-labeled natural ligand.

b(4) 105. The method according to claim 103 wherein the cells are capable of dividing or are metabolically active. *→ support is spec?*

C 1 concl. b(4) 106. The method according to claim 103 wherein the substance is present in complex natural, synthetic, or semisynthetic mixtures, and said mixtures are subjected to chromatographic separation into samples prior to said assay, wherein the luminescent-labeled non-natural ligand is added to the samples.--

REMARKS

The claims presented for consideration are 85-106. Clams 3, 11, 17-22, 23-27, and 39-84 stand withdrawn pursuant to the restriction and election of species requirements. Applicants are entitled to claims directed to non-elected species upon allowance of a generic claim.

The restriction requirement was made final by the Office action. Applicants traversal was considered unpersuasive by the examiner because applicants, allegedly, did not address PCT Rules 13.1 and 13.2, the basis of the restriction requirement. The examiner's attention, is respectfully, directed to applicants' response filed June 16, 1997 (Paper No. 12), beginning with the paragraph bridging pages 1 and 2; wherein, applicants addressed PCT Rules 13.1 and 13.2, *in detail*, and explained how the restriction made is *not* supported by PCT Rules 13.1 and 13.2.

Applicants maintain their reversal of the restriction and election of species requirements, and rights inherent therein. → how do I respond ?? 5/22/20

Claims were rejected under 35 USC §112, first paragraph, in two separate rejections for alleged lack of enablement; all claims being included in the first rejection, and the second rejection being limited to claim 4. Reconsideration of both rejections is requested.

With all due respect, both rejections are based on non-supported allegations. For example, the statement of rejection makes allegations about "the state of the art," but fails to provide any supporting evidence to substantiate the allegations. Moreover, the statement of rejection alleges that "it is expected that a variety of chemically divergent species will have, for example, similar size and rotational diffusion coefficients," again, without any supporting evidence about such an expectation. Further, the statement of rejection merely alleges the existence of "unpredictability associated with identification of a molecule via FCS," without any evidence of record cited, whatsoever, to support the allegation. In order to sustain a §112 rejection, and shift the burden to the applicant, the PTO must advance evidence inconsistent with enablement. In re Strahilevitz, 212 USPQ 561 (CCPA 1982). Since the rejection lacks any supporting evidence, applicants respectfully request that both rejections for alleged lack of enablement be withdrawn.

Claims also stand rejected under 35 USC §112, second paragraph, for

allegedly being indefinite. Reconsideration is requested in view of the instant amendment to the claims and the following remarks.

By the instant amendment, the claims have been amended to address this rejection. It is respectfully submitted that the claims, as amended hereby, satisfy the standards for definitive language set forth in §112, paragraph 2.

Further, applicants respectfully submit that, as to the rejection under §112, second paragraph, alleging indefiniteness because of "omitted steps," it must be remembered that "it is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter." Carl Zeiss Stiftung v. Renishaw PLC, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991). Explaining how the invention is to be practiced is the function of the specification; the function of the claims is to define the legal limits of the invention. In re Roberts, 176 USPQ 313, 315 (CCPA 1973).

Moreover, a patent applicant has the prerogative of claiming "less than the entire invention." Andrew Corp. v. Gabriel Electronics, Inc., 6 USPQ2d 2010, 2014 (Fed. Cir. 1988). A "patentee may claim the whole or only part of his invention." McLain v. Ortmyer, 141 U.S. 419, 423-24 (1891).

The claims were rejected in the Office action under 35 USC §102 and 35 USC §103. Reconsideration of these rejections is respectfully requested for the following reasons.

With respect to the rejections under § 102, for anticipation to exist each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. Jamesbury Corp. v. Litton Industrial Products, Inc., 225 USPQ 253 (Fed. Cir. 1985). The absence from a prior art reference of a single claim limitation negates anticipation. Kolster Speedsteel A B v. Crucible Inc., 230 USPQ 81 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. Jamesbury Corp.

Both the original claims, represented by original claim 1, and the present claims, represented by claim 85, contain the limitation, whereby, measurements are taken, in accordance with the claimed "method," in a "volume" having a maximum size of "10⁻¹⁴" liter; as recited in present claim 85, measurements are taken in a "measuring volume less than or equal to 10⁻¹⁴ l with said sample." This express limitation upon the size of the volume which is exposed to laser light, and from which laser-excited "fluorescence" is detected and measured, is not found in any of the cited references exactly as claimed in either present claim 85, or original claim 1.

Since each and every limitation of the instant claims is not found in any one of the cited references, the claims are not anticipated. Therefore, applicants respectfully submit that the rejections under 35 USC 102 should be withdrawn.

As to the rejections for alleged obviousness under §103, these rejections are traversed since the limitation on size of the "measuring volume," discussed above

with respect to the §102 rejections, would not have been an obvious modification of the teachings of any of the cited references, taken alone or in combination.

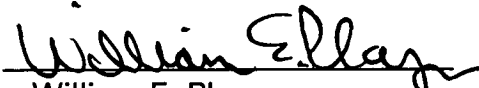
"It is facts which must support the legal conclusion of obviousness." Ex parte Crissy, 201 USPQ 689, 695 (POBdApp 1976). Modification of the prior art needed to effect the claimed invention would not have been "obvious unless the prior art suggested the desirability of the modification." In Fritch, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). In the present situation, the statements of rejection contain no indication of either how the prior art suggests the "desirability" of the measuring volume recited in the instant claims, or where among the teachings of the cited references such a desirability is to be found. When "the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the reference." In re Rigckaert, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). The PTO may not "resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis." In re Warner, 154 USPQ 173, 178 (CCPA 1967).

Since the prior art cited in the statements of rejection neither teach nor suggest a FCS procedure in which the "measuring volume" of specified size is exposed to laser light, and within which resulting fluorescence is detected and measured, in the manner presently claimed, the instant claims are not obvious over the cited art.

Favorable action commensurate with the foregoing is requested.

Respectfully submitted,

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